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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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John P. Peeters

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EXAMINER

MEHMOOD, JENNIFER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/530,901	Applicant(s) PEETERS, JOHN P.	
	Examiner JENNIFER MEHMOOD	Art Unit 2612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 22-29 is/are pending in the application.
- 4a) Of the above claim(s) 30-34 and 38-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 22-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/16/08; 4/10/08</u> | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

1. The Applicant is reminded that a complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Regarding claims 1 and 25, the phrases "capable of" and "can be" render the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-4, 8-11, 13, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson, Jr. (US 6,297,727) and further in view of Crowley (US 7,142,114) and Lu et al. (US 6,172,609).

For claim 1, Nelson discloses a diagnostics system comprising: a flexible patch having an adhesive portion and adapted to be positioned on a surface (col 3, lns 5-10; col 4, lns 51-54; Fig. 1a, item 20; Fig. 2, items 24 and 26); a radio frequency identification (RFID) tag (Fig. 1a, item 22) and said patch and having an antenna (col 6, lns 40-46; Fig. 4), an RFID electronic chip (col 6, lns 8-21; Fig. 2, item 22) associated with a unique ID (col 5, lns 59-67), said RFID tag responding to a stimulus by wirelessly transmitting, through the use of said antenna, signals that correspond to said stimulus; and a wireless RFID reader for communication with said RFID tag, said RFID reader being capable of communication over a wireless network (col 6, lns 40-55; col 8, lns 37-46; col 9, lns 1-5; Figs. 7a and 7b) and a database associated with said network, said database containing data or software associated with said ID (col 8, lns 65-67; col 9, lns 1-6, 26-30 and 40-45; col 10, lns 1-54). Nelson, however, does not disclose a sensor module. Crowley, on the other hand, discloses a sensor module associated with a unique ID (col 7, lns 20-34; col 10, lns 10-15; Fig. 1, items 40 and 54). It would have been obvious to one of ordinary skill in the art, at the time the invention was made to include a sensor module, as disclosed by Crowley, on the RFID tag, disclosed by Nelson, so that specific information of a patient, such as temperature, is obtained in order to make the most appropriate patient diagnosis. Nelson also does not disclose that a reader communicates through the use of multiple protocols with said RFID tag. Lu, however, discloses a multi-protocol wireless RFID reader for communication with said RFID tag (col 1, lns 49-55; col 2, lns 37-47), said RFID reader being capable of communicating information over a wireless network through the use of multiple

protocols. It would have been obvious to communicate through the use of multiple protocols (col 1, Ins 59-67), as disclosed by Lu, with the RFID tag disclosed by Nelson, so that a single reader is used to communicate with multiple tags, thereby providing an efficient system.

For claim 2, Nelson discloses a substantial portion of said RFID tag is integrated onto a substrate disk (Fig. 2, item 24; col 4, Ins 51-53). However, Nelson does not disclose a sensor. Furthermore, the claim is interpreted and rejected for the same reasons as stated in the rejection of claim 1 as stated above regarding the sensor disclosed by Crowley. It would have been obvious to include the sensor disclosed by Crowley integrated with the disk disclosed by Nelson so that a single medium includes both the sensor and the tag in order to decrease material costs by having two objects located on the same medium.

For claim 3, Nelson discloses said substrate disk includes a protective layer attached thereto (Fig. 2, items 24 and 26), said protective layer being in direct contact with the surface when said patch is positioned on the surface (col 4, Ins 51-67; col 5, Ins 25).

For claim 4, Nelson discloses said protective layer is formed of a semi-permeable material (col 4, Ins 56-67; col 5, Ins 1-8), but Nelson does not disclose that the layer is adapted to react to said stimulus from said surface. Crowley, however, discloses a sensor integrated with a layer that is adapted to react to said stimulus from a surface (i.e. body temperature of a human or animal; col 4, Ins 32-67; col 5, Ins 15-23). It would have been obvious to include the protective layer of Nelson adapted to

react to said stimulus from a surface as disclosed by Crowley so that specific characteristics of a human or animal are obtained to make the most appropriate diagnosis in a medical environment.

For claim 8, Nelson discloses a tag placed on a surface, but does not disclose a stimulus sensing of a surface. Crowley, however, discloses stimulus sensing includes sensing at least one electrical, chemical, biological, and physical elements of said surface (col 1, lns 5-11). It would have been obvious to include stimulus sensing of a surface so that parameters of a patient's skin are measured in a non-intrusive manner (col 1, lns 49-58), as disclosed by Crowley.

For claim 9, Nelson discloses said RFID reader, but does not specifically disclose that the reader is selected from the group consisting of a cellular telephone, a personal digital assistant, a beeper, and a computer. Crowley, discloses an RFID reader as a PDA (Fig. 5, item 10; col 7, lns 50-60). It would have been obvious to have the reader as disclosed by Nelson incorporated into a PDA, as disclosed by Crowley, so that the reader is mobile and will read several tags in multiple locations.

For claim 10, Nelson discloses said surface is the skin surface of a person (col 2, lns 60-65; col 4, lns 65-67; col 5, lns 1-8).

For claim 11, the claim is interpreted and rejected for the same reasons as stated in the rejection of claim 1 as stated above, regarding the sensor module. In addition, Nelson discloses said RFID tag further comprises a power unit adapted to stabilize voltage within said RFID tag (col 6, lns 26-48).

For claim 13, Nelson discloses an RFID tag, but does not disclose an RFID tag and sensor formed as an integrated circuit (IC). Crowley, however, discloses an RFID tag and sensor formed as an integrated circuit (IC – col 5, lns 15-20; col 6, lns 46-51). It would have been obvious to include both an RFID tag and sensor formed as an IC so that a patient easily wears the RFID tag and sensor in one location on the patient's body.

For claim 19, Nelson discloses said patch is disposable (col 5 lns 26-32).

For claim 20, Nelson discloses said RFID tag further includes a power generation module that powers said RFID tag (col 6, lns 26-39). While Nelson discloses powering said RFID tag, Nelson does not disclose an RFID tag sensor. Crowley, on the other hand, discloses powering an RFID tag sensor (col 6, lns 5-14; col 8, lns 13-15). It would have been obvious to include a power source for a RFID tag sensor so that the sensor produces and stores readings of the sensor for future reference.

7. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson, Jr. (US 6,297,727), Crowley (US 7,142,114) and Lu et al. (US 6,172,609). and further in view of Ikefuji (US 5,774,062).

For claim 5, the claim is interpreted and rejected for the same reasons as stated in the rejection of claim 1 as stated above, regarding the sensor. In addition, Nelson discloses said RFID tag comprises: and a controller communicative with an interface, said controller (RFID interrogator – col 5, lns 42-67; col 10, lns 37-56) having a memory with a data table being adapted to analyze said data within said RFID tag (Fig. 7b, items 52; col 7, lns 35-45; col 8, lns 37-47). Nelson, however, does not include a sensor

interface having an analog to digital converter coupled to at least one sensor. Ikefuji, on the other hand, discloses a sensor interface having an analog to digital converter coupled to at least one sensor (Fig. 1, item 18; Fig. 6, A/D; col 8, lns 10-15). It would have been obvious to include an analog digital converter coupled to the sensor of Crowley and interfaced with the controller of Nelson so that an abundant amount of information from the sensor is sent back to the interrogator/reader of Nelson via digital signals so that a diagnosis is made in a timely manner.

For claim 6, Nelson discloses said controller stores an ID number in a data table (col 5, lns 42-67; Fig. 1a, item 52; col 7, lns 35-45). Nelson, however, does not disclose a sensor. Crowley, on the other hand, discloses a sensor (col 7, lns 20-34; col 10, lns 10-15; Fig. 1, items 40 and 54). It would have been obvious to include a sensor ID number in the data table disclosed by Nelson in order to distinguish among several sensors that sense different types of characteristics of a patient.

For claim 7, Nelson discloses a tag communicative with said controller, but Nelson does not disclose a temperature sensor. Crowley, however, discloses a temperature sensor (col 1, lns 5-11). It would have been obvious to include a temperature sensor integrated with the tag disclosed by Nelson so that a patient's temperature is measured in a non-intrusive manner.

8. Claims 12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson, Jr. (US 6,297,727), Crowley (US 7,142,114) and Lu et al. (US 6,172,609). and further in view of Valletta (US 6,970,105).

For claim 12, Nelson discloses a patch, but does not disclose a micro knife.

Valletta, on the other hand, discloses a micro knife located on a patch adapted to dispense a substance when said patch is pressed on said surface, where said surface is the skin of the person (col 1, Ins 43-49; col 3, Ins 31-40; Fig. 2, items 13, 18, 29).

While Valletta does not specifically disclose that the micro knife (syringe) is used to draw blood from the surface of the skin, the examiner takes official notice that it is well known that the syringe may used to draw blood from the surface of the skin as well as apply a therapy as disclosed by Valletta. Furthermore, it would have been obvious to draw blood from a patch worn by a patient in order to closely monitor blood characteristics of a patient thereby providing the most appropriate treatment.

For claim 16, Nelson does not disclose a cardiac sensor. Valletta, on the other hand, discloses a cardiac sensor (col 1, Ins 47-50; col 3, Ins 1-5). It would have been obvious to detect cardiac throbs via a patch worn by a patient in order to closely monitor the heart rate of a patient to determine exercise limitations of a patient.

9. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson, Jr. (US 6,297,727), Crowley (US 7,142,114) and Lu et al. (US 6,172,609).
and further in view of Forcier et al. (US 7,061,381).

Nelson does not disclose a glucose sensor. Forcier discloses a glucose sensor (Fig. 9; col 11, Ins 65-67; col 12, Ins 1-10). It would have been obvious to modify the RFID tag of Nelson to include a glucose sensor disclosed by Forcier so that a patient is alerted to dangerous blood sugar levels.

10. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson, Jr. (US 6,297,727), Crowley (US 7,142,114) and Lu et al. (US 6,172,609).
and further in view of Quinn et al. (US 2005/0101843).

Nelson does not disclose a radiation sensor. Quinn, however, discloses a radiation sensor (Fig. 1, items 20, 24; parag 0016). It would have been obvious to modify the RFID tag of Nelson to include a radiation sensor disclosed by Quinn so that a patient is alerted to dangerous levels of radiation.

11. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson, Jr. (US 6,297,727), Crowley (US 7,142,114) and Lu et al. (US 6,172,609).
and further in view of Townsend et al. (US 6,529,127).

Nelson discloses an RFID tag, but does not disclose an RFID stress sensor. Townsend, however, discloses RF tag and sensor module includes at least one attachment point that enables attachment of the RF tag and sensor module to a structural stress, thereby forming a RF stress sensor (col 1, lns 25-47; col 2, lns 50-67; col 4, lns 8-27; Fig. 1, items 20a-20n). It would have been obvious to modify the RFID tag of Nelson to include a structural stress sensor disclosed by Townsend so that the integrity of a structure is maintained and confirmed as safe.

12. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson, Jr. (US 6,297,727), Crowley (US 7,142,114) and Lu et al. (US 6,172,609).
and further in view of Ghazarian (US 7,034,683).

Nelson discloses a reader, but does not disclose that the reader includes a processor adapted to analyze and geolocate said patch through the use of GPS.

Ghazarian, however, discloses a reader that includes a processor adapted to analyze and geolocate said patch through the use of GPS (Fig. 1A, items 32, 40, and GPS; col 10, lns 37-50; col 17, lns 49-55). It would have been obvious to incorporate a GPS receiver as disclosed by Ghazarian into the reader disclosed by Nelson so that a tag or patch's location is accounted for at all times, such as during inventory control, tracking of individuals, etc..

13. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson, Jr. (US 6,297,727), Crowley (US 7,142,114) and Lu et al. (US 6,172,609) and further in view of Lye et al. (US 2004/0100376).

Nelson discloses an RFID tag, but does not disclose a RFID sensor module integrated into an immunoassay testing strip. Lye, however, discloses a RFID sensor module integrated into an immunoassay testing strip (Fig. 3, item 12; parags 0164 and 0165). It would have been obvious to include a RFID tag sensor module integrated into an immunoassay testing strip so that particular antigens are detected and communicated to a remote location for pharmaceutical purposes.

14. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson, Jr. (US 6,297,727), Crowley (US 7,142,114) and Lu et al. (US 6,172,609) and further in view of Valletta (US 6,970,105) and Lye et al. (US 2004/0100376).

Nelson discloses a patch with a substrate, but does not disclose said patch having a sample input port enabling migration of an analyte by capillary forces; and at least one testing area integrated with said substrate area and adapted to capture antigens that flow through said testing area. Valetta discloses a sample input port

enabling migration of an analyte by capillary forces; and at least one testing area integrated with said substrate area and adapted to capture data that flow through said testing area. While Valletta discloses capturing data that flow through said testing area, Valletta does not disclose that antigens flow through said testing area. Lye, however, discloses capturing data pertaining to antigens flowing through said testing area (parags. 0148, 0159, 0164, and 0165). It would have been obvious to modify the patch disclosed by Nelson with capturing data with an input port disclosed by Valletta, specifically focusing on capturing data pertaining to antigens disclosed by Lye so that data of a patient is captured and stored for future reference, such as data deviating from a predetermined range.

15. Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley (US 7,142,114) and further in view of Lu et al. (US 6,172,609).

Crowley discloses a human diagnostics system comprising: a patch having an radio frequency identification (RFID) tag and sensor module (col 1, lns 6-11; col 6, lns 38-51), and being attachable to the surface of the skin and adapted to sense predetermined elements through the skin and transmit signals corresponding to said predetermined elements (col 4, lns 36-50); a RFID reader communicative with said patch through the use of a network (col 10, lns 37-40) to analyze, receive, and transmit the signals from said patch (col 8, lns 34-41; Fig. 1, items 10, 18, and 22); and a remote storage and data unit communicative with said RFID reader over said network (Figs. 1 and 5, item 10), said remote storage and data unit analyzing and storing data from said patch and said RFID (col 7, ln 15), said remote storage and data unit transmitting said

analyzed and stored data to said RFID reader through the use of said network; and said remote storage and data unit further having software which can be downloaded to said RFID reader for reading and interpreting said sensor (single reader for plurality of measurements/sensor tags downloaded to a database – col 4, Ins 7-20; col 8, Ins 34-42; col 10, Ins 28-40). Crowley, however, does not disclose a RFID reader communicating to a tag through the use of multiple protocols. Lu, on the other hand, discloses a RFID reader communicating to a tag through the use of multiple protocols (col 1, Ins 49-55; col 2, Ins 37-47). It would have been obvious to communicate through the use of multiple protocols with a RFID tag so that a single reader is used to communicate with multiple tags, thereby providing an efficient system.

For claim 26, Crowley discloses a remote wireless device (Fig. 5, item 10) adapted to remotely access said predetermined elements sensed by said RFID tag and sensor module (col 7, Ins 21-37; col 8, Ins 34-49).

For claim 27, Crowley discloses said predetermined elements include one or more electrical, chemical, biological, and physical element of a person (col 1, Ins 5-11).

16. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley (US 7,142,114) and Lu et al. (US 6,172,609) and further in view of Zeps et al. (US 6,937,154).

For claim 28, Crowley discloses a wireless network, but does not disclose communicating through the use of a communication protocol including, Bluetooth, Wi-Fi, Broadband, WLAN, and 3G. However, Zeps discloses communicating through the use of a communication protocol including, Bluetooth, Wi-Fi, Broadband, WLAN, and 3G

(Fig. 1; col 9, lns 30-67; col 10, lns 33-42). It would have been obvious to communicate through the use of a communication protocol so that numerous equipment communicates with one another via a standardized communication channel.

For claim 29, Crowley discloses an RFID reader as a mobile, portable device, but does not disclose the RFID reader as a cellular telephone. Zeps, however, discloses the RFID reader as a cellular telephone (Fig. 1, items 31 and 34; col 3, lns 33-45). It would have been obvious to design the reader as a cellular telephone so that the reader is used for multiple purposes such as interrogating transponders and communicating with another during an emergency.

Response to Remarks

17. Applicant's arguments filed May 7, 2008 have been fully considered but they are not persuasive.

The Applicant argues as follows:

None of the references, alone or in combination, disclose or make obvious the present invention's use of a database that includes software for reading a plurality of RFID sensors through multiple communication protocols (page 13). The remainder of the remarks (pages 14-16) contain citations of the prior art allegedly providing evidence that the art does not teach the use of a database that includes software for reading a plurality of RFID sensors through multiple communication protocols.

While the Examiner admits (see rejection to claim one in first and second office actions) that Nelson does not disclose using multiple communication protocols to read RFID sensors, Nelson discloses a database associated with a network where the

database contains software or data associated with stored identification information located in and RFID tag's memory. Nelson provides examples of a networked RFID system for the purpose of storing data files via a centralized computer database for authorization and security purposes.

Lu discloses several tags within a wireless network where a RFID reader and transponders communicate information over a wireless network through the use of multiple protocols, whereby the RFID system minimizes delays associated with identifying a specific transponder protocol.

Based on claim amendments, the Examiner maintains the position that the Crowley reference includes a sensor module that is associated with a unique ID since the sensor is part of a passive transponder where a reader interrogates (and powers the transponder) to extract data from the transponder's memory. Therefore, since Crowley explicitly describes an RFID system, the transponder and sensor combination are associated with a unique data string in order for the reader to acknowledge and identify a respective transponder.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). See MPEP § 706.07(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A Mehmood whose telephone number is (571) 272.2976. The examiner can normally be reached on M-F from 8:00am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. George Bugg, can be reached at (571) 272.2998. The fax phone number for the organization where this application or proceeding is assigned is (571) 273.8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jennifer Mehmood
June 23, 2008

/George A Bugg/
Acting SPE of Art Unit 2612